The opinion in support of the decision being entered today was <u>not</u> written for publication and is not binding precedent of the Board

Paper No. 16

## UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOSEPH P. STEINER and GREGORY S. HAMILTON

Appeal No. 2003-1169
Application No. 09/879,888

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ON BRIEF

Before WILLIAM F. SMITH, SCHEINER and PAWLIKOWSKI,  $\underline{\text{Administrative}}$  Patent Judges.

PAWLIKOWSKI, Administrative Patent Judge.

## DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 17-33.

This application is related to Application Serial Number 09/784,174 (Appeal No. 2003-1102) and Application Serial Number 09/781,427 (Appeal No. 2003-0924).

Claims 17 and 33 are representative of the subject matter on appeal, and are set forth below:

17. A pharmaceutical composition which comprises:

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(i) an effective amount of nitrogen-containing heterocyclic compound having two or more heteroatoms, wherein said compound has a substituent -C(W)-C(Y) - which is attached to a nitrogen atom of the heterocyclic ring,

wherein W and Y are independently selected from the group consisting of O, S,  $CH_2$  and  $H_2$ , and wherein said compound is additionally substituted with a ester or amide substituent attached to any atom of the heterocyclic ring other than said nitrogen atom,

provided that said ester or amide substituent is not an N-oxide of an ester or amide and further provided that said amide substituent is linked to the heterocyclic ring with a carboncarbon bond;

- (ii) a second compound for treating alopecia or promoting hair growth; and
  - (iii) a pharmaceutically acceptable carrier.
  - 33. A pharmaceutical composition which comprises:
- (i) an effective amount of a nitrogen-containing heterocyclic compound having two or more heteroatoms;

wherein said compound has a substituent -C(W)-C(Y)- which is attached to a nitrogen atom of the heterocyclic ring, wherein W and Y are independently selected from the group consisting of O, S,  $CH_2$ , and  $H_2$ , and

wherein said compound is additionally substituted with an ester or amide substituent attached to any atom of the heterocyclic ring other than said nitrogen atom,

provided that said ester or amide substituent is not an N-oxide of an ester or amide and further provided that said amide substituent is linked to the heterocyclic ring with a carboncarbon bond; and

(ii) a pharmaceutically acceptable carrier.

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The examiner relies upon the following references as evidence of unpatentability:

Li et al.	(Li '187)	5,801,187	Sep.	1, 1998
Li et al.	(Li <b>'</b> 972)	6,200,972B1	Mar. 1	3, 2001
Li et al.	(Li \544)	6,218,544B1	Apr. 1	7, 2001
Claims 5,	6, and 8 of related	Application	Serial Nu	mber

Claim 33 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Li '187, Li '972, or Li '544.

Claims 17 through 32 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 6, and 8 of related Application Serial Number 09/784,174 (Appeal No. 2003-1102).

## OPINION

We have carefully reviewed appellants' Brief and the examiner's Answer. This review has led us to conclude that the 35 U.S.C. § 102(b) rejection is well-founded. However, we cannot reach the merits of the obviousness-type double patenting rejection at this time and therefore remand this application to the examiner in connection with this rejection.

I.

With regard to the 35 U.S.C. § 102(b) rejection, the examiner states that the compound recited in appellants' claim 33 and the compound of Formula I in each of the Li references are the same for the reasons explained on pages 3 and 4 of the Answer.

In response, appellants state "[h]ow can a disclosure of a compound, like that of the '187 patent's Formula I, anticipate a composition, like that of present claim 33?" Appellants repeat a similar position for each of the Li references. Brief, pages 3-4.

In response, on page 6 of the Answer, the examiner states that she did explain that each of the Li references anticipates the composition set forth in claim 33 for the reasons provided on pages 3-4 of the answer. We agree with the examiner's position and understanding of each of the Li references. Appellants do not point to any differences between the compound recited in claim 33 and the compound set forth in Formula I of each of the Li references.

We therefore affirm the 35 U.S.C. § 102(b) rejection of claim 33.

With regard to the provisional rejection under the doctrine of obviousness-type double patenting, the examiner states that the instant claims read on claims 5, 6, and 8 of Application Serial No. 09/784,174 (Appeal No. 2003-1102) "when J and K in '174 form a heterocyclic ring". Answer, pages 4-6.

In response, appellants argue that "[o]verlap itself, however, cannot establish a prima facie case of nonstatutory double patenting." Brief, page 5.

We note that the determination of obviousness-type double patenting essentially involves the determination of obviousness under 35 U.S.C. § 103, except that the first patent disclosure is not applicable as "prior art." See, e.g., Chisum, § 9.03[3]. In In re Longi, the Federal Circuit discussed the similarity between rejections under § 103 and "obviousness-type" double patenting:

We note that the Board did not make the instant rejection under § 103. However, a double patenting of the obviousness type rejection is "analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. § 103" except that the patent principally underlying the double patenting rejection is not considered prior art. In re Braithwaite, 379 F.2d 594, 600, n.4, 54 C.C.P.A. 1589, 1597, n.4, 154 USPQ 29, 34 (1967). Therefore, our analysis concerning the correctness of the Board's decision in the instant case parallels our previous guidelines for a § 103 rejection. See, e.g., In re De Blauwe, 736 F.2d 699, 222 USPQ 191 (Fed. Cir. 1984).

<u>In re Longi</u>, 759 F.2d at 892 n.4, 225 USPQ at 648 n.4.

Because the analysis regarding obviousness-type double patenting essentially involves the determination of obviousness under 35 U.S.C. § 103, we note that obviousness under Section 103 is a legal conclusion based upon facts revealing the scope and content of the prior art, the differences between the prior art and the claims at issue, the level of ordinary skill in the art, and objective evidence of nonobviousness. Graham v. John Deere

Co., 86 S.Ct. 684, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). Upon return of the application, the examiner is therefore to reweigh the entire merits of the obviousness-type double patenting rejection according to the criteria set forth in Graham v. John Deere Co.

Furthermore, in the case of <u>In re Lee</u>, 277 F.3d 1338, 1445, 61 USPQ2d 1430, 1435 (Fed. Cir. 2002), the Court stressed the import of articulating and making of record knowledge negating patentability. The examiner is therefore also to reweigh the entire merits of the rejection and make of record any facts supporting her position negating patentability.

In specific response to appellants' statement that "[o]verlap itself, however, cannot establish a prima facie case of nonstatutory double patenting", the examiner is to reweigh the entire merits of the obviousness-type double patenting rejection in light of In re Kaplan, 789 F.2d 1574, 1577-1581, 229 USPQ 678,

681-683 (Fed. Cir. 1987). In this context, the examiner should expound on the obviousness-type double patenting rejection according to the analysis set forth in <u>In re Baird</u>, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) and <u>In re Jones</u>, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992).

III.

Claim 17 recites "an effective amount". Upon return of the application, the examiner is to consider what amount is meant by this phrase, and for what purpose, and whether this phrase is indefinite under 35 U.S.C. § 112, second paragraph.

IV.

In conclusion, we affirm the anticipation rejection.

However, with regard to the provisional rejection under the judicially created doctrine of obviousness-type double patenting, and with regard to the matter raised in Section III, we remand the application to the examiner to attend to these matters.

This application, by virtue of its "special" status, requires an immediate action, MPEP § 708.01(d). It is important that the Board be informed promptly of any action affecting the appeal in this case.

## AFFIRMED-IN-PART REMANDED-IN-PART

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William F. Smith
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

Beverly A. Pawlikowski
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